UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,100	11/02/2000	Joseph Wang	37000UT9917	4989

5179 7590 08/26/2003

PEACOCK MYERS AND ADAMS P C
P O BOX 26927
ALBUQUERQUE, NM 871256927

EXAMINER	
MUTSCHLER, BRIAN L	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/705,100	WANG ET AL.
	Examiner	Art Unit
	Brian L. Mutschler	1753

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-63 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 02 November 2000 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

   a. On page 14 at line 19, please insert --be-- after "may".

   b. On page 16 at line 2, please change "controller" to --controlled--.

   c. On page 21 at line 19, please change "id" to --is--.

   d. On page 22 at line 4, please insert --may-- after "which".

   e. On page 22 at line 7, please change "**142**" to **--132--**.

   Appropriate correction is required.

Claim Comments

2. In claim 1, the thick-film electrode has no ascribed purpose, i.e., providing an application point for the electrokinetic driving force or for detection.

3. Regarding claims 1 and 39, the phrase "thick-film electrode" uses relative terminology that does not distinguish what constitutes a "thick-film" electrode.

4. It is noted that claim 18 depends from claim 16 instead of claim 17, which recites a similar limitation. Claim 51, which is similar to claim 18, depends from claim 50, which addresses similar features. Either form is acceptable.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-38 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "a fluidic transport" in line 6. As defined in the specification and also recited in claims, the fluidic transport is a *method* of transporting the fluid; specifically, in line 1 of claim 6, the fluidic transport is defined as comprising "at least one method". Since claim 1 is an apparatus claim, it is suggested that the limitation be changed to define the limitation in structural terms, such as --a fluidic transport means-- as recited in the abstract. The phrase "fluidic transport" also occurs in claim 2 at line 1 and claim 5 at line 1. The same applies to dependent claims 2-38.

Claim 14 recites the limitation "the amperometric detection system comprises at least one member selected from the group consisting of fixed potential and potential-step amperometric detection". This limitation is indefinite because fixed potential and potential-step detection are methods of detection and not detection systems. It is suggested that the limitation be changed by adding --system-- after "detection" in line 3 to positively recite a structural limitation.

Claim 62 recites the limitation "said nucleic acid is selected" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the limitation be changed to --said nucleic acids are-- as introduced in claim 61.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-7, 9-20, 25-28, 32, 33, 35-40 and 42-63 rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (WO 98/09161) in view of Wang et al. ("Performance of screen-printed carbon electrodes fabricated from different carbon inks", ELECTROCHIMICA ACTA, Vol. 43, No. 23, pp. 3459-3465 (1998)).

Regarding claims 1, 38 and 42, Mathies et al. disclose an apparatus and a method of using the apparatus comprising a first substrate **11** having capillary channels formed therein, and a second substrate (top plate) **14** bonded to the first substrate **11** (page 6, lines 2-16). Electrodes for electrochemical detection can be fabricated on the second substrate **14** (page 6, lines 25-27). Mathies et al. describe the conventional chips as having a plurality of separation channels **12** (page 6, lines 2-16; figure 1). Separations are performed by applying a potential across the channel (see figure 3).

Regarding claims 2-6 and 43-45, the fluidic transport system comprises a conductive system using electrodes and a high-voltage power supply to power the electrodes and create an electrokinetic fluid transport (page 7, line 1 to page 8, line 2; fig. 23).

Regarding claims 7, 10-14, 40, 46 and 47, Mathies et al. disclose the use of a reference electrode, electrical contacts to the electrodes and an analyte analysis system

connected to the detection electrode (page7, line 1 to page 9, line 30). The analysis system uses amperometric detection and can use stepped or fixed potential detection (page 9, line 17 to page 10, line 32).

Regarding claims 17, 18, 50 and 51, the separation channel has a width of 1-2000 μm, with a preferable width between 1-500 μm (page 7, line 29 to page 8, line 2).

Regarding claims 25-27 and 57-59, the detection electrode may comprise metals or carbon (page 6, lines 25-31).

Regarding claim 28 and 32, the apparatus comprises at least one cavity (reservoir) in fluidic connection with the separation channel (page 9, lines 1-16; fig. 3).

Regarding claim 33, Mathies et al. disclose that conventional apparatuses have a plurality of separation channels (page 6, lines 2-16; fig. 1).

Regarding claims 34, 36 and 37, Mathies et al. show the first and second substrates **11** and **14** as substantially planar and parallel (0° angle) to each other, with the second substrate bonded (sealed) to the first substrate (page 6, lines 2-31).

Regarding claims 38 and 63, the channels contain a separation matrix (polyacrylamide) (page 6, lines 13-14; page 13, lines 21-22).

Regarding claim 54, the distance between the detection electrode and the outlet of the microfluidic channel is fixed since the second substrate is bonded to the first substrate (page 6, lines 2-16).

Regarding claim 60, Mathies et al. disclose the use of a solution containing a buffer (page 9, lines 1-16).

Regarding claims 61 and 62, Mathies et al. disclose the use of nucleic acids, including DNA, and other compounds such as dopamine, epinephrine and catechol (page 12, line 15 to page 14, line 2).

The apparatus and method of Mathies et al. differs from the instant invention because Mathies et al. do not disclose the following:

a. A thick-film electrode, as recited in claims 1 and 39.

b. The second substrate is a ceramic, polymeric or plastic substrate, as recited in claim 9.

c. A stripping potentiometry system and a voltammetric detection system, as recited in claims 15 and 48.

c. The thick-film electrode is a screen-printed electrode, as recited in claims 16 and 49.

d. The thick-film electrode has a thickness from about 1 μm to about 100 μm, as recited in claims 19 and 52.

e. The thick-film electrode has a thickness from about 8 μm to about 30 μm, as recited in claims 20 and 53.

f. The thick-film electrode is a carbon ink electrode, as recited in claims 25 and 57.

g. The distance between the thick-film electrode and the outlet end of the microfluidic channel is from about 1 μm to about 500 μm, as recited in claim 55.

h. The distance between the thick-film electrode and the outlet end of the microfluidic channel is from about 50 μm to about 100 μm, as recited in claim 56.

Regarding claims 1 and 39, the phrase "thick-film electrode" uses relative terminology that does not distinguish what constitutes a "thick-film" electrode. However, with regard to claims 1, 16, 25, 39, 49 and 57, Wang et al. disclose the use of "thick-film" electrodes comprising screen-printed carbon ink electrodes for microfabricated sensors and also teaches that such sensors are desirable because the are "extremely inexpensive" and are "highly reproducible electrochemical sensors" (see Abstract and Introduction).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus and method of Mathies et al. to use screen-printed, carbon ink thick-film electrodes as taught by Wang et al. because such electrodes are extremely inexpensive and highly reproducible.

Regarding claim 9, Wang et al. discloses the use of a ceramic substrate on which the electrode is formed (see "Screen-printing fabrication").

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the second substrate of Mathies et al. to use a ceramic substrate because ceramic substrates are mechanically strong and stable at a wide range of temperatures.

Regarding claims 15 and 48, Wang et al. disclose the use of pulse-voltammetric, amperometric and stripping operations to measure the currents using the detection electrodes (see Abstract).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus and method of Mathies et al. to use a voltammetric or stripping detection system as taught by Wang et al. because such detection systems allow the measurement of a wide range of electrochemical reactivities.

Regarding claims 19, 20, 52, 53, 55 and 56, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrodes and distances in the apparatus and method of Mathies et al. to use such ranges because the electrode thickness and separation distance are result effective variables that are dependent upon the electrode material and the reaction being analyzed, respectively. Different reactions and different materials all have different properties that would require an obvious variation in the operating parameters in the apparatus and method.

9. Claims 8, 30, 31 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (WO 98/09161) in view of Wang et al. ("Performance of screen-printed carbon electrodes fabricated from different carbon inks", ELECTROCHIMICA ACTA, Vol. 43, No. 23, pp. 3459-3465 (1998)), as applied above to

claims 1-7, 10-20, 25-28, 32, 33, 35-40 and 42-63, and further in view of Freemantle ("Downsizing chemistry", C&EN, pp. 27-35 (Feb. 22, 1999)).

Mathies et al. and Wang et al. describe an apparatus and method having the limitations recited in claims 1-7, 10-20, 25-28, 32, 33, 35-40 and 42-63 of the instant invention, as explained above in section 8.

The apparatus and method described by Mathies et al. and Wang et al. differ from the instant invention because they do not disclose the following:

a. The first substrate is a fused-silica, silica-based, polymer, plastic or elastomer substrate, as recited in claim 8.

b. A buffer cavity and a sample cavity in fluidic connection with the inlet end of the separation channel, as recited in claim 29.

c. A reaction cavity in fluidic connection with the inlet end of the separation channel, as recited in claim 30.

d. A plurality of separation channels with the inlet ends in fluidic connection with the cavity, as recited in claim 31.

e. The method comprises providing at least one reactant for the analyte and mixing the reactant and the analyte prior to analyzing the analyte at the thick-film electrode, as recited in claim 41.

Regarding claim 8, Freemantle teaches that laboratory microchips may be made of many materials including glass, quartz, plastic or polymers and "each material has its own advantages and disadvantages" (see Making chips on page 28). For example,

"Polymers have the potential of being mass produced inexpensively" (see Making chips on page 28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the substrate of Mathies et al. to use a material such as a polymer because Freemantle teaches that polymer substrates have the potential to be mass produced inexpensively.

Regarding claims 29, 30 and 41, Freemantle discloses a system comprising a sample cavity, a buffer cavity, a reagent cavity, and a reaction chamber, all in fluid communication with the separation channel (see figure on page 31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus of Mathies et al. to use a buffer cavity, a sample cavity, a reactant cavity and a reaction chamber in fluid communication with one another before the separation channel (and the detector) as taught by Freemantle because such features allow the performance of a wider range of chemical reactions and the ability to analyze the results of such reactions in a unified system.

Regarding claim 31, Freemantle also shows another example of a plurality of separation channels connected to a cavity (see figure on page 33).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus of Mathies et al. to use a plurality of separation channels on a single chip connected to a cavity as shown by Freemantle

because the use of a plurality of separation channels allows the device to perform multiple separations simultaneously.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Pat. No. 6,274,089 issued to Chow et al. provides several examples of different chip designs to perform different reactions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (703) 305-0180. The examiner can normally be reached on Monday-Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

blm
August 19, 2003